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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/423,259	03/02/2000	CATHERINE HANNI	97- MA- CNR-VI	6537

466 7590 09/10/2002

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EXAMINER	
EINSMANN, JULIET CAROLINE	
ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 09/10/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/423,259	Applicant(s) HANNI ET AL.	
	Examiner Juliet C Einsmann	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 June 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17-23 and 25-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *22* is/are allowed.

6)☒ Claim(s) *17-19,21,23 and 25-27* is/are rejected.

7)☒ Claim(s) *20* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02 March 2000* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. This action is written in response applicant's correspondence submitted 6/21/02, paper number 22. Claim 22 has been amended. Claims 17-23 and 25-27 are pending. Also with the response was filed a declaration under rule 132 (paper number 23). Two copies of the declaration were received, an original, unexecuted copy and a faxed, executed copy. these have been stapled together and placed in the file as paper number 23. Applicant's amendments, declaration, and arguments have been thoroughly reviewed, but are not persuasive for the reasons that follow. Any rejections not reiterated in this action have been withdrawn. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. **This action is final.**

Claim Rejections - 35 USC § 103

2. Claims 17-19, 21, 23 and 25-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Loftus *et al.* (PNAS USA, Vol. 91, pp. 2757-2761, March 1994) in view of Fei *et al.* (Animal Science and Technology (1996) Vol. 67, No. 10, pp. 900-905).

Loftus *et al.* teach the sequences of the D loops of the mtDNA from a number of cattle breeds. These sequences are fully disclosed in GenBank accession numbers L27712-27737. Instant SEQ ID NO: 2 consists of the complement of nucleotides 685-699 of the sequence disclosed in GenBank Accession number L27725 (see attached GenBank record). Instant SEQ ID NO: 5 consists of nucleotides 230-244 of the sequence disclosed in GenBank Accession number L27725.

Furthermore, the sequence taught by Loftus *et al.* and fully disclosed in GenBank accession number L27725 also comprises instant SEQ ID NO: 9-14. Instant SEQ ID NO: 9 consists of nucleotides 19-43, instant SEQ ID NO: 10 consists of the complement of nucleotides 158-177, instant SEQ ID NO: 11 consists of the complement of nucleotides 358-377, instant SEQ ID NO: 12 consists of nucleotides 441-60, instant SEQ ID NO: 13 consists of nucleotides 715-734, and instant SEQ ID NO: 14 consists of the complement of nucleotides 854-873.

Instant SEQ ID NO: 8 consists of nucleotides 225-705 of the sequence disclosed in GenBank Accession number L27725. Therefore, this sequence taught by Loftus *et al.* also comprises instant SEQ ID NO: 7 (nucleotides 310-336) and 19 (nucleotides 423-447), which are merely segments of SEQ ID NO: 8.

Instant SEQ ID NO: 15 consists of nucleotides 15824-15981 of the sequence disclosed in GenBank Accession number L27725.

Instant SEQ ID NO: 16 consists of nucleotides 225-337 of the sequence disclosed in GenBank Accession number L27725.

Instant SEQ ID NO: 17 consists of nucleotides 441-705 of the sequence disclosed in GenBank Accession number L27725.

Instant SEQ ID NO: 18 consists of nucleotides 745-902 of the sequence disclosed in GenBank Accession number L27712 (see attached GenBank record).

Loftus *et al.* do not teach nucleic acids which consist of the instantly claimed nucleic acids, nor do they teach primer pairs which comprise oligonucleotides that consist of the instantly disclosed sequences.

Fei *et al.* teach methods for specific identification of meat from cattle using the PCR with primers designed to amplify portions of the mitochondrial D-loop DNA sequence (p. 900-905). Primer BF taught by Fei *et al.* consists of nucleotides 397-416 of the sequence taught by Loftus *et al.* The primer taught by Fei *et al.* is considered to be a functional homologue of all of the primers and probes of the instantly claimed invention, since the primer disclosed by Fei *et al.* possesses the same function as those of the instant invention, namely to amplify and/or detect portions of the D loop mtDNA from cattle.

In light of the sequences taught by Loftus *et al.* and the teaching by Fei *et al.* that beef samples can be specifically identified by PCR amplification of the D-loop of mitochondrial DNA, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have selected any primers from the sequences taught by Loftus *et al.* in order to have provided functional homologues of the primers taught by Fei *et al.* The selection of different primer pairs from the sequences taught by Loftus *et al.* would have provided the ordinary practitioner with additional mechanisms for the specific amplification and detection of D-loop mitochondrial DNA from beef products in meat samples. The ordinary practitioner would have had a more than reasonable expectation of success since Fei *et al.* teach that amplification with primers specific for the D-loop mtDNA of cattle results in the ability to detect small amounts of beef in a mixed meat sample, for example 0.1% of beef in pork.

Response to Remarks

The declaration has been carefully reviewed but is not sufficient to overcome the maintained rejection for the reasons that follow.

The MPEP states that "Whether the unexpected results are the result of unexpectedly improved results or a property not taught by the prior art, the "objective evidence of nonobviousness must be commensurate in scope with the claims which the evidence is offered to support... the showing of unexpected results must be reviewed to see if the results occur over the entire claimed range (MPEP 716.02(d))." In this case, the declaration refer(s) only to the primers and probes described in the above referenced application and not to the individual claims of the application. Thus, there is no showing that the objective evidence of nonobviousness is commensurate in scope with the claims. See MPEP § 716. Nonetheless, some of the claims are drawn to particular primer pairs consisting of particular nucleic acids (claims 20 and 22), and with regard to these claims, it is clear that the unexpected results are commensurate in scope with the claims, though the claims are not mentioned in the declaration itself. This is not the case with the remaining rejected claims.

In the instant case, the evidence provided in the declaration is not commensurate in scope with the claims provided in claims 17, 18, 19, and 21. These claims are all drawn to primers and pairs of primers that have not been shown to have unexpected results commensurate in scope with the claims themselves.

Claims 17, 18, and 21 encompasses primers that are shorter than SEQ ID NO: 1, SEQ ID NO: 3, SEQ ID NO: 4, SEQ ID NO: 6, SEQ ID NO: 9, SEQ ID NO: 10, SEQ ID NO: 11, SEQ ID NO: 12, SEQ ID NO: 13 and SEQ ID NO: 14. There is no showing in the declaration or the specification that these particular primers have the same unexpected results as the mentioned pairs of primers. The specificity of a particular oligonucleotide is largely dependent on its

sequence. There is no demonstration that these shorter primers retain the same high degree of specificity as the sequences from which they are taken.

Claims 17 and 19 encompass pairs of primers that have SEQ ID NO: 2 or SEQ ID NO: 5. There is no showing in the declaration or the specification that these particular primers have the same unexpected results as the mentioned pairs of primers. The specificity of a particular oligonucleotide is largely dependent on its sequence. These primers differ from the primers SEQ ID NO: 3 and SEQ ID NO: 6 because they are shorter than SEQ ID NO: 3 or SEQ ID NO: 6. There is no demonstration that these shorter primers retain the same high degree of specificity as SEQ ID NO: 3 and SEQ ID NO: 6.

The evidence provided in the declaration in insufficient to establish non-obviousness with regard to claims 23, 25, 26, and 27. Each of these claims is drawn to nucleic acids consisting of particular nucleic acid probes identified by sequence identifier. With regard to nucleic acid probes consisting of these sequences, the declaration asserts "we clearly show (see figures 9-11) that the PCR fragments (SEQ ID NO: 8 and SEQ ID NO: 15-17) can specifically hybridize with various sets of probes derived from SEQ ID NO: 7, SEQ ID NO: 15, SEQ ID NO: 17, and SEQ ID NO: 19 (Figures 9-11) (see declaration pages 2-3)." Aside from this discussion, there is no other mention of the sequences recited in claims 23, 25, 26, and 27.

Figure 9 demonstrates that probes "derived from" SEQ ID NO: 17, SEQ ID NO: 19 and SEQ ID NO: 7 hybridize to an amplified section of beef mitochondrial DNA but not to a section of pork mtDNA that was amplified using the same primers. This is not sufficient to overcome the obviousness type rejection with regard to claim 23 (drawn to nucleic acids consisting of at least 15 and up to all nucleotides of SEQ ID NO: 7 or SEQ ID NO: 19) because it is not clear

how the probes "derived from" SEQ ID NO: 7 and SEQ ID NO: 19 relate to the probes claimed in claim 23. It is not clear if the probes "derived from" SEQ ID NO: 7 and SEQ ID NO: 19 are shorter than or longer than SEQ ID NO: 7 or SEQ ID NO: 19. Even if this figure were sufficient to establish the non-obviousness of nucleic acids consisting of SEQ ID NO: 7 and SEQ ID NO: 19, the claim is not so limited so the result would not be commensurate in scope with the claim.

With regard to claim 25, which is drawn to a DNA fragment consisting of SEQ ID NO: 8, figure 10 is not sufficient to establish the non-obviousness of this claim. The figure legend of figure 10 asserts that SEQ ID NO: 8 is beef specific since it cannot be obtained using pork DNA as a template. However, this line of reasoning is not persuasive, absent evidence that SEQ ID NO: 8 is in fact beef specific. This figure merely demonstrates that primers SEQ ID NO: 3 and SEQ ID NO: 6 are beef specific. It does not demonstrate that the entire 498 base pair fragment that is SEQ ID NO: 8 has the same level of specificity. Further, the figure legend points out that the beef specific probes derived from SEQ ID NO: 17, 19, and 7 hybridize to SEQ ID NO: 8. This is not an unexpected result since SEQ ID NO: 8 is a fragment of bovine mtDNA and these probes are designed to hybridize to a fragment of bovine mtDNA that is contained within SEQ ID NO: 8.

Figure 11 is not sufficient to establish the non-obviousness of claims 26 or 27 for largely the same reasons that figure 10 was not sufficient to establish the non-obviousness of claim 25. The figure legends of figure 11 asserts that SEQ ID NO: 15, 16, 17, and 18 are beef specific since they cannot be obtained using pork DNA as a template. However, this line of reasoning is not persuasive, absent evidence that these particular sequences are in fact beef specific. These figures merely demonstrate that primers that produce SEQ ID NO: 15, 16, 17, and 18 are beef

specific. It does not demonstrate that the full length amplification products that are SEQ ID NO: 15, 16, 17, and 18 have the same level of specificity as the primers that amplify them. Further, the figure legend points out that the beef specific probes hybridize to SEQ ID NO: 15, 16, 17, and 18. This is not an unexpected result since SEQ ID NO: 15, 16, 17, and 18 are a fragment of bovine mtDNA and these probes are designed to hybridize to a fragment of bovine mtDNA that is contained within SEQ ID NO: 15, 16, 17, and 18.

Thus, the rejections of record are maintained with regard to claims 17-19, 21, 23 and 25-27.

Claim Objections

3. Claim 20 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Allowable Subject Matter

4. Claim 22 is allowed.

5. The following is a statement of allowable subject matter as well as reasons for the indication of allowable subject matter: Claims which require the presence of nucleic acids consisting of SEQ ID NO: 3 or consisting of SEQ ID NO: 6 are unobvious over the prior art. While the prior art provides longer sequences which comprise SEQ ID NO: 3 and SEQ ID NO: 6, and the prior art provides motivation to design primers for the amplification of bovine mtDNA, this teaching is not sufficient to obviate nucleic acids which consist of SEQ ID NO: 3 or SEQ ID NO: 6. These nucleic acids are considered to be unobvious in light of the unexpected results provided in the specification, wherein these nucleic acids are shown to amplify bovine

mtDNA but not that of horse, sheep, pig, duck, chicken or turkey (Figure 1). Further, nucleic acids consisting of SEQ ID NO: 3 and SEQ ID NO: 6 are shown to amplify mtDNA from many different breeds (Figure 2).

6. Nucleic acids consisting of SEQ ID NO: 1 and SEQ ID NO: 4 are also unobvious over the prior art of record because these nucleic acids comprise SEQ ID NO: 3 and SEQ ID NO: 6. It is assumed that, although slightly longer, these nucleic acids would function as primers with the same level of specificity as SEQ ID NO: 3 and SEQ ID NO: 6.

7. Primer pairs consisting of SEQ ID NO: 11 and SEQ ID NO: 6, SEQ ID NO: 3 and SEQ ID NO: 12, SEQ ID NO: 12 and SEQ ID NO: 14, SEQ ID NO: 9 and SEQ ID NO: 10, and SEQ ID NO: 13 and SEQ ID NO: 14 are all allowable in light of the declaration paper number 23. This declaration demonstrates that these primers amplify bovine mtDNA but not that of sheep, pork, horse, chicken or humans (figures 2-6 of the declaration). Furthermore, the declaration provides that the primer pairs taught by Fei et al. do not have the same range of specificity (figures 7 and 8 of the declaration), and the instantly allowed primers have superiority in a property the claimed primers share with the prior art (i.e. the ability to specifically detect bovine mtDNA). Thus, claim 22 is non-obvious in view of the art of record.

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Juliet C. Einsmann whose telephone number is (703) 306-5824. The examiner can normally be reached on Monday through Thursday, 7:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 and (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600

Juliet C. Einsmann
Examiner
Art Unit 1634

September 6, 2002